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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,867

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Michael Horstmann

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3928

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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT

PAPER NUMBER

3771

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,867	<b>Applicant(s)</b> HORSTMANN ET AL.	
	<b>Examiner</b> KRISTEN C. MATTER	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,9 and 12-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9 and 12-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input checked="" type="checkbox"/> Other: <u>WO 03/053413</u> |

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### **DETAILED ACTION**

This Action is in response to the amendment filed 9/10/2010. Claims 1, 4, 5, 8, 9, 13, 19, 20 and 26 have been amended, claims 7 and 11 have been cancelled, and no claims have been added. Thus, claims 1-6, 8, 9, and 12-30 are currently pending in the instant application.

### ***Response to Arguments***

Applicant's arguments filed 9/10/10 have been fully considered and are persuasive. Specifically, neither Honeycutt nor Hill disclose the preparations being "dissolved or dispersed" in the polymer matrix as defined by one of ordinary skill in the art (i.e., both references have an already polymerized matrix dipped/coated in the preparations so that the preparation fills previously formed voids within the solid polymer matrix).

However, upon further consideration, a new ground(s) of rejection is made in view of Muller et al. and Martyn et al.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 28-30 are rejected under 35 U.S.C. 103(a) as obvious over Honeycutt (4,765,348) in view of Baker et al. (US 5,721,257, herein referred to**

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**as “Baker”), Martyn et al. (WO 2003/053413, herein referred to as “Martyn”), and Ek et al. (US 2005/0053665, herein referred to as “Ek”).**

Regarding claims 1, 2, 5, 8, 12, 14, 22, 23, 26, and 30, Honeycutt discloses a device for administration of nicotine to the human body by inhalation (column 1, lines 37-45) for the purpose of being a non-combustible simulated cigarette (column 1, 8-10), wherein the device comprises a first preparation (18) containing a free base of nicotine (column 1, lines 45-46) which is contained by absorption in a polytetrafluoroethylene element (column 3, lines 11-18), and a second preparation (20) containing a volatile acid (column 1, lines 46-52), such as acetic acid (column 2, line 39) which is separated from the first preparation (18) by an impermeable partition (24) (column 2, lines 48-49). The device contains a first air inlet, located to the right of section 18 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #18 in figure 3, a second air inlet, located to the right of section 20 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #20 in figure 3, a common flow path (22) where the two airstreams from the separate sections combine simultaneously due to inhalation and an outlet aperture (16) where the common flow path leads to (column 2, lines 60-69), all of which have a conduit cross-section.

Honeycutt lacks the first and additional preparations comprising a polymer matrix with the agent and acid being contained in a dissolved or dispersed form. However, Baker discloses a smoking cessation device with nicotine and/or additive salts including acetic acid (column 7, lines 20-25) dispersed (column 8, lines 20-35) within a PMMA polymer matrix (column 10, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have dispersed the nicotine and/or acid of Honeycutt in a polymer matrix

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as taught by Baker in order to safely deliver a slow release of nicotine to a user for smoking cessation. In addition, Baker teaches the device for transdermal delivery. However, Martyn teaches a similar slow release composition in which therapeutic agents (including acids) are dispersed in a polymer matrix (abstract) and can be used in either transdermal or inhalation therapy (see claims 10 and 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the dispersed form of preparations taught by Baker for inhalation therapy in the modified Honeycutt/Baker device since at the time of the invention it was well known that such compositions were interchangeable as taught by Martyn.

Honeycutt is also silent as to the exact flow rates and nicotine release. However, Ek discloses that during inhalation therapy, depending on flow resistance, etc. an average amount of 8-10 micrograms of nicotine is released per puff from nicotine contained within cellulose matrices (paragraph 106). Therefore, absent a critical teaching and/or showing of unexpected results from such flow rates, examiner contends that puffs from 1-10 seconds at 0.1-1 L/min are well known as common for smokers and that with such puffs, release of 5-250 micrograms of the nicotine would have been obvious because such amounts are common in the art as taught by Ek and the exact amount would depend on how much nicotine was dispersed in the matrix, the puff strength, flow properties of the device, etc.

Likewise, Honeycutt is silent as to particle size and negative pressure differential. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with appropriate size elements to create airflows and chemical balances necessary to operate the device successfully (column 3, lines 1-10), since it has been held that discovering an optimum value of a result effective variable involves only

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routine skill in the art. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Plus, particles of less than 10 microns are well known as appropriate for allowing delivery of particles to a user's airways.

Regarding claim 6, Honeycutt discloses the chemical balance between volatized nicotine and acid can be controlled (column 3, lines 1-10), but does not disclose the exact ratio of the chemical balance. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that during inhalation a ratio of equimolar quantities of the nicotine and acid could be released in order to provide the advantage of giving the vapor a neutral pH.

Regarding claim 28 and 29, Honeycutt discloses the device having an impermeable part (24) (column 2, lines 48-49) as well as discloses that the device can be made of any material (column 2, lines 11-13), but does not disclose a definite composition of the whole device. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the entire device out of the impermeable material of impermeable partition (24) and for this material to be a polyester material coated with a copolymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See *In re Leshin*, 125 USPQ 416.

**Claims 3, 4, 9, 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 28-30 above, and further in view of Ray (4,284,089).**

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Regarding claims 3, 4, 9, 24, 25 and 27 Honeycutt does not disclose the preparations containing a solvent suitable for inhalation. Ray teaches a preparation containing water as a solvent as well as menthol dissolved in ethanol as a flavoring (column 4, lines 23-28; column 7, lines 14-22). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with solvents as taught by Ray in order to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

**Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 230 above, and further in view of Turner (5,400,808).**

Regarding claims 28 and 29, Honeycutt does not disclose the entire device being made from a material which is impermeable. Turner teaches a nicotine impermeable container constructed of aluminum foil coated with a copolymer of acrylonitrile and methyl acrylate (column 2, lines 36-41). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt a material as taught by Turner in order to provide the advantage a longer shelf life of the contents of the inhaler.

**Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 28-30 above, and further in view of Ferre (726,037).**

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Regarding claim 13, Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. Ferre teaches an inhaler with separate impermeable (lines 53-54) compartments (a, c) that have orifices (f) that can be opened or closed (line 70). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with a sealable compartments as taught by Ferre, and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive disposable sealing means.

**Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 28-30 above, and further in view of Kallstrand (5,660,169).**

Regarding claims 15-21 Honeycutt discloses the claimed structure of the invention, including the oblong recesses as discussed above in the rejection of claim 1, except for a part formed by deep-drawing. Kallstrand discloses an inhaler device with an upper (1) and bottom part (2), containing a compartment with a peelable seal (figs. 3a-c), formed by deep-drawing (column 2, lines 11-14). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the inhaler of Honeycutt with deep-drawn components as taught by Kallstrand in order to provide the advantage of an inexpensive way to manufacture the device.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/  
Examiner, Art Unit 3771